February 26, 2020

Integra Lifesciences Corp.
Diana Bordon
311 Enterprise Dr.
Plainsboro, New Jersey 08536

Re: K081635
Trade/Device Name: Integra Meshed Bilayer Wound Matrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: June 6, 2008
Received: June 11, 2008

Dear Diana Bordon:

This letter corrects our substantially equivalent letter of December 04, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kimberly Ferlin -S

Kimberly M. Ferlin, Ph.D.
Assistant Director (acting)
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081635

Device Name: **INTEGRA™ Meshed Bilayer Wound Matrix**

Indications For Use: INTEGRA™ Meshed Bilayer Wound Matrix is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds. The device may be used in conjunction with negative pressure wound therapy. The device is intended for one-time use.

Prescription Use _X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081625

K081635

510(K) SUMMARY

INTEGRA™ Meshed Bilayer Wound Matrix

DEC 04 2008

Submitter's name and address:

Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536 USA

Contact person and telephone number:

Diana Bordon
Director, Regulatory Affairs
Telephone: (609) 275-0500
Fax: (609) 275-9445

Date Summary was prepared:

June 4, 2008

Name of the device:

Proprietary Name:	INTEGRA™ Meshed Bilayer Wound Matrix
Common Name:	Wound Dressing
Classification Name:	Dressing, Wound, Drug
Product Code:	FRO

Substantial Equivalence:

INTEGRA™ Meshed Bilayer Wound Matrix is substantially equivalent in function and intended use to INTEGRA™ Bilayer Matrix Wound Dressing, which has been cleared to market under Premarket Notification 510(k) K021792.

Device Description:

INTEGRA™ Meshed Bilayer Wound Matrix is an advanced wound care device comprised of a porous matrix of cross-linked bovine tendon collagen and glycosaminoglycan with a polysiloxane (silicone) layer. The meshed bilayer matrix allows drainage of wound exudate and provides a flexible adherent covering for the wound surface. The collagen- glycosaminoglycan biodegradable matrix provides a scaffold for cellular invasion and capillary growth.

Intended Use:

INTEGRA™ Meshed Bilayer Wound Matrix is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds. May be used in conjunction with negative pressure wound therapy. The device is intended for one-time use.

Testing and Test Results:

INTEGRA™ Meshed Bilayer Wound Matrix and INTEGRA™ Bilayer Matrix Wound Dressing (K021792) are comprised of identical materials and are processed and sterilized by identical methods. Biocompatibility testing including Cytotoxicity, Dermal Sensitization, Irritation, Acute Systemic Toxicity, Pyrogenicity and Hemolysis were conducted for the INTEGRA Bilayer Matrix Wound Dressing product, in accordance with International Standard ISO 10993-1:1992, *Biological evaluation of medical devices – Part 1: Guidance on selection of tests* and with Good Laboratory Practices. All test results were acceptable. These test results are applicable to the meshed product because, as noted above, the dressings are comprised of the same materials.

In addition to biocompatibility testing, the product is tested to meet the following performance characteristics. Pore size is determined using SEM and Image Analysis to provide a pre-determined functional pore size. In order to ensure that the native helical configuration of collagen is not significantly altered in the manufacturing process, the helical content in the collagen-glycosaminoglycan sponge is evaluated using Fourier Transform Infrared (FTIR) Spectrophotometry. Chondroitin-6-sulfate (C-6-S) is quantified using visible spectroscopy. The degree of cross-linking is determined using a colorimetric assay.

Conclusion

The results of the *in vitro* product characterization studies, performance testing and biocompatibility data demonstrate that INTEGRA Meshed Bilayer Wound Matrix is safe and substantially equivalent to its predicate device.